CENTER FOR DRUG EVALUATION AND RESEARCH .

APPLICATION NUMBER: 21-075

MICROBIOLOGY REVIEW(S)

KMG

REVIEW FOR HFD-510 OFFICE OF NEW DRUG CHEMISTRY MICROBIOLOGY STAFF MICROBIOLOGIST'S REVIEW #1 OF NDA

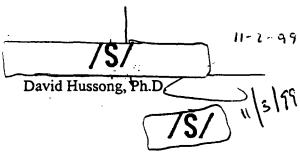
NOV | 3 1999

November 2, 1999

A.	1.	NDA	21-075	
		SPONSOR	Genentech, Inc.	
			One DNA Way	
			South San Francisco, CA 94080	
	2.	PRODUCT NAMES Hormone])	(Nutropin Depot [recombinant Human Growth	
	3.	DOSAGE FORM AND ROUTE OF ADMINISTRATION: A sterile powder for re-suspension in Diluent, packaged in a kit that includes one vial of Nutropin Depot (13.5 mg, 18 mg, or 22.5 mg dosage unit), one vial of Diluent for Nutropin Depot, three 21-gauge needles, and a patient and physician's insert.		
	4. METHOD(S) OF STERILIZATION: The Nutron		ERILIZATION: The Nutropin Depot is prepared by	
		The state of the s	uent for Nutropin Depot is	
	5.	PHARMACOLOGIC microspheres	CAL CATEGORY: Growth hormone, sustained release	
	6.	DRUG PRIORITY (CLASSIFICATION: 3P	
B.	1.	DATE OF INITIAL	SUBMISSION: June 25, 1999	
	2.	DATE OF AMEND	MENT: (none)	
	3.	RELATED DOCUM	TENTS: DMF	
), and IND	rHGH).	
	4.	ASSIGNED FOR RI	<u>EVIEW</u> : July 16, 1999	
C.	a reco	REMARKS: This NDA is based on IND The NDA describes the manufacture of a recombinant protein drug substance by Genentech through its processing into a microspheres, and processing as a powder for suspension in a diluent for injection. The submission refers to DMF for the manufacture of the diluent packaged with the microspheres. The DMF refers to DMF for the information specific to the facilites used to		

manufacture of the diluent (in vials) that is packaged as part of this finished product.

D. <u>CONCLUSIONS</u>: The application is recommended for APPROVAL.



cc:

HFD 160/Consult File HFD 510/CSO/C. King HFD 510/Chemist HFD 805/D. Hussong

Drafted by: D. Hussong, 11/02/99 R/D initialed by: P. Cooney

APPEARS THIS WAY ON ORIGINAL